1642

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re the application of: Kimberly A. Gillis et al.

Application No.: 09/997,424

Confirmation No. 6432

Filed: November 28, 2001

For: Expression Analysis of SMARC Nucleic Acids And Polypeptides Useful In The Diagnosis And Treatment of Prostate Cancer

Attorney Docket No.: 102729-16 (AM100494)

Group Art Unit: 1642

Examiner: Minh Tam Davis

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

TRANSMITTAL LETTER

Dear Sir:

Enclosed are the following documents for filing in connection with the above-referenced patent application:

1. Response to Restriction/Election Requirement with marked pages; and
2. Return Receipt Postcard.

The Commissioner is hereby authorized to charge any underpayments or overpayments in connection with this filing to our Deposit Account No. 141449, Reference No. 102729-16, Customer No. 021125. A duplicate copy of this sheet is enclosed.

I hereby certify that this correspondence is deposited with the United States Postal Service as first class mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on:

August 27, 2003
Date

Jasbir Sagoo, Ph.D., Reg. No. 51,177

Respectfully submitted,

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August 27, 2003		By:
Date of Signature and Mail Deposit		Jasbir Sagoo, Ph.D. Reg. No: 51,177

RESPONSE TO RESTRICTION/ELECTION REQUIREMENT

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

In the Office Action mailed from the Patent Office on July 29, 2003, the Examiner required election of one of the following patentably distinct groups:

Groups 1-24:	Claims 1-10, 16;
Groups 25-48:	Claims 1-7, 11-16;
Groups 49-72:	Claims 17-21;
Groups 73-96:	Claims 17-21;
Group 97:	Claims 22, 33;

Group 98:	Claims 22, 33;
Group 99:	Claim 23;
Group 100:	Claim 23;
Group 101:	Claim 24;
Group 102:	Claim 24;
Group 103:	Claims 25-26;
Group 104:	Claims 25, 27;
Group 105:	Claims 28-29;
Group 106:	Claims 30-31; and
Group 107:	Claim 32.

At the outset, Applicants thank the Examiner for pointing out the inconsistency in the application where "SMARCD1" and "SMARCD3" markers (*See* page 2, lines 23, page 78, line 22, and 31 page 79, line 20, as well as the claims) are incorrectly stated as "SMARC1" and "SMARC3," respectively (*See* page 73, lines 31-32, page 74, line 16 and 27-28, page 75, line 7 and 10, and page 78, line 3, lines 8-10). Applicants present marked paragraphs showing the corrections.

Applicants also wish to note that the invention is directed to using SWI/SNF related matrix associate action dependent regulator of chromatin (SMARC), as genetic markers for the detection, diagnosis and prognosis of prostate disorders. The invention provides methods and screening assays for the detection and diagnosis of prostate cancer, as well as for testing for compounds that effect the expression levels of SMARC in prostate cancer. The SMARC family has a number of family members, such as SMARCD3 and SMARCD1.

Applicants respectfully traverse the restriction requirement as improper. However, for the purpose of being responsive to the outstanding Office Action, Applicants hereby elect the Groups 25-48 invention, with traverse. If required to elect a specific SMARC marker, Applicants elect SMARCD3, with traverse. The invention of Groups 25-48 is drawn to methods of assessing whether a subject is afflicted with prostate cancer by determining the mRNA level of one or more SMARC markers. Reconsideration and withdrawal of the restriction requirement is requested because the invention is drawn to measuring the expression levels of SMARC (e.g., SMARCD3 or SMARCD1)

associated with prostate cancer. The expression level can be monitored by either measuring the nucleic acids associated with SMARC (e.g., RNA, or DNA), or the SMARC protein levels.

The restriction requirement states that "the number of possible combination of SMARC markers was determined by a factorial calculation, that is 4 factorial or 24 possible combinations." Applicants respectfully traverse this rejection because there are two SMARC markers (e.g., SMARCD3 or SMARCD1). Accordingly, the number of groups of inventions will be reduced.

Moreover, Applicants have presented a generic linking claim directed to the SMARC family of markers that exhibit an altered expression associated with prostate cancer. The Examiner concedes that linking claims are presented. Thus, upon allowance of a linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn with regard to any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s).

For the sake of clarity, the following arguments will be presented based on the different groups outlined in the Restriction Requirement. The Restriction Requirement has separated the various claims into groups that determine the *protein* level of the SMARC markers, in class 435, subclass 7.1 (Groups 1-24, 49-72, 97, 99, 100, 103, and 105), and those claims directed to the *mRNA* level of the SMARC markers, in class 435, subclass 6 (Groups 25-48, 73-76, 98, and 104). Furthermore, the Restriction Requirement states, at page 6, that:

> "The methods of groups 1-107 are distinct from each other because they differ at least in objectives, method steps, reagents and/or dosages, and/or schedules used, response variables and criteria for success.
>
> The species are distinct because they have different properties."

From this, it is clear that the Examiner has taken the position that methods and reagents required to detect proteins are different from those required to detect nucleic acids. Thus, a more appropriate grouping should be based on methods for detecting nucleic acids as being patentably distinct from methods for detecting proteins. With this in mind, claims 1-10, 16 (Group 1-24), claims 17-21 (Group 49-72), claims 22 and 33 (Group 97), claim 23 (Group 99), claims 25-26, (Group 103), as well as claims 28-29 (Group 105), all of which are in class 435, subclass 7.1, should be grouped together as being directed to measuring *proteins*. On the other hand, claims 1-7, 11-16

(Group 25-48), claims 17-21 (Group 73-96), claims 22 and 33 (Group 98), claim 23 (Group 100), and claims 25 and 27 (Group 104) are all in class 435, subclass 435, subclass 6, and should be grouped together as being directed to measuring *nucleic acids*.

This is a more appropriate grouping because the methods and reagents required to detect the expression of SMARC nucleic acids to assess whether a subject is afflicted with prostate cancer (Group 25-48), are the same methods and reagents required to assess the progression of prostate cancer (Group 73-96), the efficacy of a therapy (Group 98), to assess a potential test compound that may trigger prostate cancer (Group 100), or to identify a compound useful for treating prostate cancer (Group 104). Despite the fact that there are different objectives, e.g., some claims involve incubating the sample with test compounds and observing the effects of such compounds on SMARC nucleic acid expression levels, the ultimate methods and reagents for detecting the effects of such compounds remains the same. That is to say that, irrelevant of whether the expression levels of nucleic acids associated with SMARC are measured in the presence or absence of a test compound, the expression levels will nevertheless, still be measured using the same reagents to detect the nucleic acids (e.g., reverse transcriptase-PCR). Furthermore, it is conceded in the Restriction Requirement that Groups 25-48, 73-96, 98, 100, and 104 belong to the same class/subclass of 435/6. Thus, searching for Groups 25-48 invention will inherently also involve search for Groups 73-96, 98, 100, and 104 inventions. Accordingly, a single search would suffice for claims 1-7, 11-16 (Group 25-48), 17-21, (Group 73-96), 22 and 33 (Group 98), 23 (Group 100), and 25 and 27 (Group 104).

Furthermore, claim 24 (Group 102), claims 30-31 (Group 106) also involve measuring *nucleic acids*, and as such should be grouped with all claims directed to detecting nucleic acids.

Claims that are directed to measuring protein levels of SMARC markers are claims 1-10, 16 (Group 1-24), claims 17-21 (Group 49-72), claims 22 and 33 (Group 97), claim 23 (Group 99), claims 25-26 (Group 103), as well as clams 28-29 (Group 105), are all in class 435, subclass 7.1. As such, these claims should be grouped together as directed to detecting *polypeptides* that require the same reagents. Again, a more appropriate grouping is one that uses the same reagents to detect the expression of the SMARC polypeptide to assess whether a subject is afflicted with prostate cancer (Group 1-24), as well as to assess progression of prostate cancer (Group 49-72), assess the efficacy

of therapy (Group 97), potential test compounds that may trigger prostate cancer (Group 99), or to identify compounds useful for treating prostate cancer (Group 103 and 105). As before, even though there are different objectives, the reagents and methods used to measure SMARC polypeptide levels will nevertheless remain the same. It is conceded in the Office Action that Groups 1-24, 49-72, 97, 99, 103 and 105 belong to the same class/subclass of 435/7.1. Thus searching for Group 1-24 inventions will inherently also involve searching for Group 49-72, 97, 99, 103 and 105 inventions. Accordingly, a single search would suffice for claims in these groups.

Furthermore, claim 24 (Group 101) and claim 32 (Group 107) are also directed to inhibiting protein expression of SMARCD3, or detecting the effects of compounds on prostate cancer by measuring *protein activity*, and as such should be grouped with all claims directed to detecting polypeptides.

With regard to the two-way election of species requirement, Applicants elect the species of cells collected from a prostate gland (claim 4 of Groups 25-48), with traverse.

The Examiner is urged to call the undersigned at the telephone number indicated below so that any remaining issues can be discussed.

Respectfully submitted,
NUTTER, McCLENNEN & FISH, LLP

Date: August 27, 2003

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